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| APPLICATION NO.                                                              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/019,643                                                                   | 03/20/2002  | Richard Fayer-Hosken | 235.00300101        | 1109             |
| 26813                                                                        | 7590        | 09/22/2004           |                     | EXAMINER         |
| MUETING, RAASCH & GEBHARDT, P.A.<br>P.O. BOX 581415<br>MINNEAPOLIS, MN 55458 |             |                      | NOLAN, PATRICK J    |                  |
|                                                                              |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                              |             |                      | 1644                |                  |

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                     |                         |  |
|------------------------------|-------------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>              | <b>Applicant(s)</b>     |  |
|                              | 10/019,643                          | FAYRER-HOSKEN ET AL.    |  |
|                              | <b>Examiner</b><br>Patrick J. Nolan | <b>Art Unit</b><br>1644 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 June 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 4,6,12-21,23 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 4, 6, 12-21, 23, 27-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6-25-04.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

1. Claims 4, 6, 12-21, 23 and 27-29 are pending.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4, 6, 12-21, 23 and 27-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a reproductive disease that is related to egg laying or fertilization, does not reasonably provide enablement for treating cystic hyperplasia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments received 6-25-04 have been fully considered but are not found persuasive.

Applicant argues that cystic hyperplasia is related to fertilization and so therefore inhibiting fertilization with the zona pellucida composition the condition is treatable.

However in reviewing Applicant's references it is clear the reproductive structures do reorganize during a typical estrus cycle in chickens and that in humans cystic hyperplasia rarely leads to cancer, although sometimes it does. Since Applicant is attempting to provide a nexus between cystic hyperplasia and fertilization the Examiner reviewed treatment methods for cystic hyperplasia and found that the Merck Manual for Diagnosis and Therapy clearly states that cystic hyperplasia, a possible cause of dysfunctional uterine bleeding, is treated by inhibiting the menstrual cycle with medroxyprogesterone, not by inhibiting fertilization. In other words fertilization and the resulting pregnancy does not cause cystic hyperplasia, so inhibiting it would not be expected to treat it.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

  
Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

September 20, 2004